AUG - 5 2011

510(K) Summary – K110959

SUMMARY OF SAFETY AND EFFECTIVENESS

March 31, 2011 – Revised July 1, 2011

NAME OF FIRM:
OrthoPediatrics, Corp.
2850 Frontier Drive
Warsaw, Indiana 46582
Establishment Registration No.: 9102640

510(K) CONTACT:
Mark Fox
Vice President of Regulatory Affairs
Tel: (574) 268-6379
Fax: (574) 269-3692

TRADE NAME: OrthoPediatrics Blade Plate System

COMMON NAME: Bone Plates and Bone Screws

RECOMMENDED CLASSIFICATION:

21 CFR 888.3030: Single/Multiple components metallic bone fixation appliances and accessories. Class II per 21 CFR §888.3030

21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener., Class II per 21 CFR §888.3040

Recommended Class: II

DEVICE PRODUCT CODE(S): HRS, (Plate, Fixation, Bone)
HWC, (Screw, Fixation, Bone)

SUBSTANTIALLY EQUIVALENT DEVICES:

K083286, PediLoc Locking Plate System, OrthoPediatrics

K100240, PediLoc Tibial Plate System, OrthoPediatrics

K082949, OrthoPediatrics Bone Screws, OrthoPediatrics

K993289,Bone Plate System (TC-100 Plating System) Blade Plates, Smith & Nephew

Pre Ammendment – Osteotomy / Blade Plates, Smith & Nephew

K110959(3/3)

DEVICE DESCRIPTION:

The **OrthoPediatrics Blade Plate System** will combine implants and instruments in one convenient system. This system will offer the advantages of the osteotomy blade plates and cannulated instrumentation. Osteotomy plates provide ease of reduction and good rotational stability while maintaining bone stock. Cannulated instruments work over a guide wire for precise placement and safety.

INDICATIONS:

The **OrthoPediatrics Blade Plate System** is intended for fixation of long bone fractures and osteotomies in all pediatric subgroups (except neonates) and in small stature adults. Specific indications include: intertrochanteric derotation and varus osteotomies, femoral neck and pertrochanteric fractures, intertrochanteric valgus osteotomies, proximal and distal tibial osteotomies and humeral fractures and osteotomies.

MATERIALS:

The devices are manufactured from 316L stainless steel which meets the ASTM-F138 standard.

TECHNOLOGIC CHARACTERISTICS:

The fundamental scientific principles and technological characteristics, including the intended use, material, sizes, and general design are the same as, or similar to, the predicate devices.

Summary of technological characteristics:

1. Plate thickness(s) and width(s) are substantially equivalent to predicates.

2. Identical materials to cited predicates.

3. Range of plate angles are substantially equivalent to predicates.

4. Range of screw sizes and threads are substantially equivalent to predicates.

5. Indications for Use is substantially equivalent to predicates.

The technological characteristics of the subject device and the predicates are substantially equivalent to the predicates.

PERFORMANCE ANALYSIS:

Subject device has similar configuration, sizes and design as the predicate device(s). Engineering calculations with worst case loading calculations of subject device and corresponding predicate device, confirmed that subject device has equivalent or better strength and resistance to bending moments. A review of the MAUDE complaint data base of similar predicate devices support the safety and effectiveness of the device.

FUNCTION:

The system functions to provide immediate stability and temporary fixation during the natural healing process.

EQUIVALENCY:

Therefore, since materials, intended use, and technological features used in the **OrthoPediatrics Blade Plate System** are similar to the predicate devices, safety and efficacy is expected to be equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OrthoPediatrics, Corp.
c/o Mr. Mark Fox
Vice President of Regulatory Affairs
2850 Frontier Drive
Warsaw, Indiana 46582

AUG - 5 2011

Re: K110959
Trade/Device Name: OrthoPediatrics Blade Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single / multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: August 3, 2011
Received: August 3, 2011

Dear Mr. Fox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

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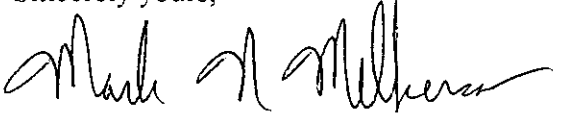
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K110959

Device Name: OrthoPediatrics Blade Plate System

INDICATIONS:

The **OrthoPediatrics Blade Plate System** is intended for fixation of long bone fractures and osteotomies in all pediatric subgroups (except neonates) and in small stature adults. Specific indications include: intertrochanteric derotation and varus osteotomies, femoral neck and pertrochanteric fractures, intertrochanteric valgus osteotomies, proximal and distal tibial osteotomies and humeral fractures and osteotomies.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Mellerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110959